

Notice of Allowability	Application No.	Applicant(s)	
	09/993,291	SHAPIRO ET AL.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to July 13, 2007.
2. ☒ The allowed claim(s) is/are 30-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Introduction

1. This communication is in response to the Applicants' communication dated July 13, 2007. Claims 30-39 of the application are pending.

Reasons for Allowance

2. Claims 30-39 of the application are allowed over prior art of record.
3. The following is an Examiner's statement of reasons for the indication of allowable subject matter:

The closest prior art of record shows:

(1) visual modeling and dynamic simulation of complex biological systems; a hierarchy of compartments represent time intervals and spatial and functional structure of complex system; graphical description of the entities represent both the mathematical models and the information within the modular components; the descriptive information, data and the mathematical models are all encapsulated within modular components; the models are built by interconnecting the icons resulting in a complex network of multidimensional pathways; the models represent the states of the entities and the events that cause the transitions from one state to another; the models simulate the dynamics of pools of entities in each state; the methods create and display

Art Unit: 2123

interactive network of pathways; the models show evolutionary tree representing alternative successive states that a compartmentalized model may follow; the components of each type of cell is modeled and analyzed at increasing levels of detail; signal transmission through pathways within each cell in repeated cycles, driven by external cycles is modeled (**Thalhammer-Reyero**, U. S. Patent 6,983,227);

(2) methods and systems for testing how well a network model represents a biological pathway in a biological systems; knowledge of the biological pathway of action of a drug is important to drug developers; the inputs and outputs of the network are modeled using binary values; the interactions are modeled using a network of logical operators relating input cellular constituents to output classes of cellular constituents using simple rules of combination; the methods provide complete and efficient experiments for testing the network model which compare the relative changes in the biological system in response to perturbations in the network; the method also provides for determining the overall goodness of fit of the network model to the biological system by predicting from the network model how output classes behave in response to chosen experiments (**Stoughton et al.**, U. S. Patent 6,132,969);

(3) a method and apparatus for modeling cellular structure and function, using theoretical hypotheses of cellular physiology; the hypotheses are formalized into mathematical models and tested by incorporating the models into simulations; a simulation volume is created and simulation is performed by modeling the behavior, physiological and/or anatomical, of the simulation elements making up the simulation volume; the simulations establish a model as a set of ordinary and partial differential equations that represent the cellular physiology of interest; the method allows complex intercellular chemical simulations to be built; geometric models,

Art Unit: 2123

simulation elements and original 3D images can all be rendered into a 3D scene; the method allows direct comparison of simulation results with experimental data; by comparing the simulation results with experimental results, the user can confirm the hypotheses (**Schaff et al.**, U. S. Patent 6,708,141); and

(4) an interactive modeling system that models biological systems from cellular, subcellular to human or patient population level; the models represent the biological system in a hierarchical manner of varying levels of complexity; the models allow developing clinical trial designs; the models simulate interrelated biological behavior at cellular and subcellular levels to better predict and successfully alter clinical outcomes manifested as symptoms of diseases; the models reflect changes over time at each level of system hierarchy; an entity at a level is comprised of one or more inputs, a graphical element representing synthesis of the inputs and one or more outputs; Knowledge diagrams (KD) are constructed to represent the knowledge collected and are used for building the models; knowledge diagrams show the cell pools in the model; connection between cell pools in the model are based on state change links in the KD; these connections provide pathways for the flow of cells from one pool to another cell pool (**Fink et al.**, U. S. Patent 5,808,918).

None of these references taken either alone or in combination with the prior art of record discloses an automated method for simulating a developmental process of an organism, specifically including:

(Claim 30) “b) representing the organism or a tissue within the organism by a graph data structure, wherein the graph data structure comprises:

Art Unit: 2123

- i) a list of links, each link representing the interaction between two cells;
- ii) a lineage tree recording the family tree of cell birth for the cells represented by the list of links; and
- iii) a list of nodes, each node representing a cell of the cells represented by the list of links, with an embedding describing the location of the cell in Cartesian coordinates and a set of differential equations describing the time evolution of the location of the cell, said differential equations comprising the initial condition values and process parameters, each node comprising a model that comprises a system of differential equations and associated parameters describing the developmental process”.

None of these references taken either alone or in combination with the prior art of record discloses an automated method for simulating a developmental process of an organism, specifically including:

(Claim 31) “b) representing the organism or a tissue within the organism by a graph data structure, wherein the graph data structure comprises:

- i) a list of links, each link representing the interaction between two cells;
- ii) a lineage tree recording the family tree of cell birth for the cells represented by the list of links; and
- iii) a list of nodes, each node representing a cell of the cells represented by the list of links, with an embedding describing the location of the cell in Cartesian coordinates and a set of differential equations describing the time evolution of the location of the cell, said differential equations comprising the initial condition values and process parameters, each node comprising

Art Unit: 2123

a model that comprises a system of differential equations and associated parameters describing the developmental process”.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance.”

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez, can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC 2100 Group receptionist: 571-272-2100.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

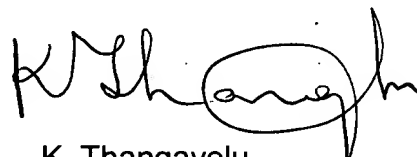
Art Unit: 2123

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'K. Thangavelu'. The signature is stylized with a large, circular loop at the end of the last name.

K. Thangavelu
Art Unit 2123
August 3, 2007